

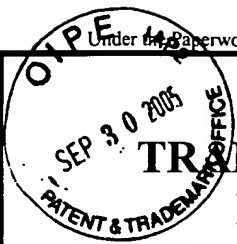
10-03-05

PTO/SB/21 (01-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

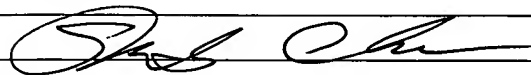
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

 <b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/782,521	
	Filing Date	February 18, 2004	
	First Named Inventor	Rajashree Joshi-Hangal	
	Art Unit	1614	
	Examiner Name	Not yet assigned	
Total Number of Pages in This Submission		Attorney Docket Number	12636-303.301

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): return receipt postcard
<div style="border: 1px solid black; padding: 5px;"> <b>Remarks</b>    </div>		

**SIGNATURE OF APPLICANT, ATTORNEY OR AGENT**

Firm or Individual name	Shirley Chen, Reg. No. 44,608, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	September 30, 2005

**Express Mail Date: September 30 , 2005****Express Mail Label No.: EV518897445US**

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



EXPRESS MAIL LABEL NO.: EV 518897445 US

PATENT  
Attorney Docket No. 12636-303.301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Rajashree JOSHI-HANGAL, et al.

Group Art Unit: 1614

Serial Number: 10/782,521

Examiner: Not yet assigned

Filing Date: February 18, 2004

CONFIRMATION NO: 4711

Title: METHOD FOR PREPARING AND  
USING POLYOXYETHYLATED CASTOR  
OIL IN PHARMACEUTICAL  
COMPOSITIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.97**

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;  
-- OR --
- ☒ (3) It is being filed before the mailing date of the first Office Action on the merits;  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;  
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.  
-- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.  
-- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☒ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☒ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- DE 19925211 was published in German. A translation of the abstract in English language is sufficient to convey the scope of its disclosure.
- EP 0515540, EP 0593601, EP 0671912, EP 0788492, EP 0876362 and EP 1045709 were published in German. The English language abstracts, titles, claims and the drawings are sufficient to convey the scope of their disclosure.
- WO 9316060, WO 9323389, WO 9407880 and WO 98/57630 were published in French. The English language abstracts and the drawings are sufficient to convey the scope of their disclosure.
- Should the Examiner believe that a complete translation of any of the above mentioned publications is necessary to understand their disclosure, Applicants will endeavor to provide such translations at the Examiner's request.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-303.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

By: 

Shirley Chen, Reg. No. 44,608

Dated: September 30, 2005

650 Page Mill Road  
Palo Alto, CA 94304-1050  
(650) 493-9300  
Customer No. 021971



Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449/PTO</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/782,521
				Filing Date	February 18, 2004
				First Named Inventor	Rajashree Joshi-Hangal
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	1	of	7	Attorney Docket Number	12636-303.301

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US 2001/0029264	10/11/2001	McChesney-Harris	
		US 2003/0143184	07/31/2003	Seo, et al.	
		US 2003/0153614	08/14/2003	Joshi-Hangal, et al.	
		US 2003/0187062	10/02/2003	Zenoni, et al.	
		US 4814470	03/21/2989	Colin, et al.	
		US 4942184	07/17/1990	Haugwitz, et al.	
		US 5254580	10/19/1993	Chen, et al.	
		US 5403858	04/04/1995	Bastard, et al.	
		US 5681846	10/28/1997	Trissel	
		US 5703117	12/30/1997	Mayhew, et al.	
		US 5922754	07/13/1999	Burchett, et al.	
		US 6040330	03/21/2000	Hausheer, et al.	
		US 6046230	04/04/2000	Chung, et al.	
		US 6090844	07/18/2000	Han, et al.	
		US 6121313	09/19/2000	Gao, et al.	
		US 6388112	05/14/2002	Anevski	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/782,521
				Filing Date	February 18, 2004
				First Named Inventor	Rajashree Joshi-Hangal
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	2	of	7	Attorney Docket Number	12636-303.301

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		DE 19925211	12/07/2000	Peter Ortner		✓
		EP 0498482B	09/08/1999	Elan Pharma International Ltd.		
		EP 0515540B	07/06/1994	Rhone-Poulenc Rorer S.A.		✓
		EP 0593601B	12/17/1997	Rhone-Poulenc Rorer S.A.		✓
		EP 0645145B	03/12/1997	Bristol-Myers Squibb Company		
		EP 0661969B	03/12/2003	The Government of the USA		
		EP 0671912B	03/22/2000	Rhone-Poulenc Rorer S.A.		✓
		EP 0674510	08/05/1998	Napro Biotherapeutics, Inc.		
		EP 0684813 (WO 94/18954)	09/01/1994	Clover Consolidated, Ltd.		
		EP 0706373	07/19/2000	Georgetown University		
		EP 0750495	12/04/2002	R.P. Scherer Technologies, Inc.		
		EP 0768876	08/16/2001	Hemagen/PFC		
		EP 0773938	02/03/1999	Indena S.p.A.		
		EP 0788492	03/31/1999	Rhone-Poulenc Rorer S.A.		✓
		EP 0835657	08/25/2004	Mayne Pharma (USA) Inc.		
		EP 0876362	09/24/2003	Aventis Pharma S.A.		✓
		EP 0941089	05/16/2001	Angiotech Pharmaceuticals, Inc.		
		EP 0960107	10/02/2002	Bristol-Myers Squibb Company		
		EP 0998279	10/16/2002	Man Han, et al.		

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/782,521
				Filing Date	February 18, 2004
				First Named Inventor	Rajashree Joshi-Hangal
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	3	of	7	Attorney Docket Number	12636-303.301

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		EP 1045709B	12/03/2003	Bayer Aktiengesellschaft		✓
		EP 1315484 (WO 01/72299)	10/04/2001	Baker Norton Pharmaceuticals, Inc.		
		EP 1332755	08/06/2003	Nanjing Zhenzhong Bioengineering Company Ltd.		
		EP 1340497	09/03/2003	Novagali SAS		
		EP 1374864	01/02/2004	Nunich Biotech AG		
		EP 1387677 (WO 02/058694)	08/01/2002	Dana-Farber Cancer Institute, Inc.		
		EP 1395256 (WO 02/083067)	10/24/2002	Cryolife, Inc.		
		EP 1423107 (WO 02/076404)	10/03/2002	Protarga, Inc.		
		EP 1427407 (WO 02/076402)	10/03/2002	Protarga, Inc.		
		EP 1435908 (WO 03/022248)	03/20/2003	Korea Institute of Science and Technology		
		EP 1461029 (WO 03/057208)	07/17/2003	IVAX Research, Inc.		
		EP 1465618 (WO 03/053350)	07/03/2003	Bristol-Myers Squibb Company		
		EP 1467722 (WO 03/059332)	07/24/2003	Angiotech Pharmaceuticals, Inc.		
		EP 1479382	11/24/2004	IVAX Research, Inc.		
		EP 1490348 (WO 03/080587)	10/02/2003	Pharmacia Italia SPA		
		EP 1496888 (WO 03/086383)	10/23/2003	Gabriele Multhoff		
		EP 1498143	01/19/2005	Aventis Pharma S.A.		
		EP 1501501 (WO 03/047630)	06/12/2003	Andras Bertha, et al.		
		EP 1503779 (WO 03/053219)	07/03/2003	Voyager Pharmaceutical Corporation		

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/782,521
				Filing Date	February 18, 2004
				First Named Inventor	Rajashree Joshi-Hangal
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	4	of	7	Attorney Docket Number	12636-303.301

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		EP 1509209 (WO 03/099264)	12/04/2003	UMD, Inc.		
		EP 1515751 (WO 03/103714)	12/18/2003	Pliva-Lachema A. S.		
		EP 1545499 (WO 04/009075)	01/29/2004	Korea Institute of Science and Technology		
		EP 1545500 (WO 04/009076)	01/29/2004	Korea Institute of Science and Technology		
		EP 1556001 (WO 04/041118)	05/21/2004	UMD, Inc.		
		EP 1556030 (WO 04/037211)	05/06/2004	Bristol-Myers Squibb Company		
		EP 1558241 (WO 04/043390)	05/27/2004	Bristol-Myers Squibb Company		
		GB 2388025	11/05/2003	Pharmaceutical Bulk Substances S/A		
		WO 91/18613	12/12/1991	Research Corporation Technologies, Inc.		
		WO 93/00424	01/07/1993	Worcester Polytechnic Institute		
		WO 93/16060	08/19/1993	Rhone-Poulenc Rorer S.A.		✓
		WO 93/21338	10/28/1993	The Research and Development Institute, Inc.		
		WO 93/23389	11/25/1993	Rhone-Poulenc Rorer S.A.		✓
		WO 94/05282	03/17/1994	The Scripps Research Institute		
		WO 94/07880	04/14/1994	Rhone-Poulenc Rorer S.A.		✓
		WO 94/12172	06/09/1994	Thomas Jefferson University		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*



Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/782,521
				Filing Date	February 18, 2004
				First Named Inventor	Rajashree Joshi-Hangal
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	5	of	7	Attorney Docket Number	12636-303.301

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		WO 96/29070	09/26/1996	The Board of Regents, The University of Texas System		
		WO 9640192	12/19/1996	Avmax, Inc.		
		WO 97/15269	05/01/1997	Baker Norton Pharmaceuticals, Inc.		
		WO 97/23208	07/03/1997	Genelabs Technologies, Inc.		
		WO 97/41850	11/13/1997	Song, et al.		
		WO 97/45105	12/04/1997	Angiotech Pharmaceuticals, Inc.		
		WO 98/35554	08/20/1998	Canji, Inc.		
		WO 98/38862	09/11/1998	Bristol-Myers Squibb Company		
		WO 98/47360	10/29/1998	Bristol-Myers Squibb Company		
		WO 98/57630	12/23/1998	Laboratoires Thissen		✓
		WO 99/06024	02/11/1999	Pharmacia & Upjohn Company		
		WO 99/33780	07/08/1999	Schein Pharmaceutical, Inc.		
		WO 99/45918	09/16/1999	Napro Biotherapeutics, Inc.		
		WO 99/49848	10/07/1999	RTP Pharma Inc.		
		WO 99/65307	12/23/1999	Baker Norton Pharmaceuticals, Inc.		
		WO 00/09114	02/24/2000	Octamer, Inc.		
		WO 00/23070	04/27/2000	Ben Venue Laboratories, Inc.		
		WO 00/32186	06/08/2000	Mylan Pharmaceuticals, Inc.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/782,521
				Filing Date	February 18, 2004
				First Named Inventor	Rajashree Joshi-Hangal
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	6	of	7	Attorney Docket Number	12636-303.301

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		WO 00/33862	06/15/2000	Pharmasolutions, Inc.		
		WO 00/40236	07/13/2000	Dietl, Hans		
		WO 00/50007	08/31/2000	Lipocine, Inc.		
		WO 00/53592	09/14/2000	Asahi Kasei Kogyo Kabushiki Kaisha		
		WO 00/64437	11/02/2000	American Biosciences, Inc.		
		WO 00/74653	12/14/2000	Skyepharma, Inc.		
		WO 00/78247	12/28/2000	Baker Norton Pharmaceuticals, Inc.		
		WO 01/12229	02/22/2001	Galena AS		
		WO 01/30448	05/03/2001	Baker Norton Pharmaceuticals, Inc.		
		WO 01/52838	07/26/2001	Baker Norton Pharmaceuticals, Inc.		
		WO 01/52893	07/26/2001	Theryte Ltd.		
		WO 02/03957	01/17/2002	Guilford Pharmaceuticals, Inc.		
		WO 02/056878	07/25/2002	Pharmacia Corporation		
		WO 02/064214	08/22/2002	F. Hoffmann-La Roche AG		
		WO 02/09695	02/07/2002	Atossa Healthcare, Inc.		
		WO 02/13815	02/21/2002	Hanmi Phar Co., Ltd.		
		WO 02/43765	06/06/2002	Transform Pharmaceuticals, Inc.		
		WO 03/007914	01/30/2003	Guilford Pharmaceuticals, Inc.		
		WO 03/007915	01/30/2003	Guilford Pharmaceuticals, Inc.		
		WO 03/022247	03/20/2003	Choongwae Pharma Corporation		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449/PTO

*(Use as many sheets as necessary)*

Application Number	10/782,521
--------------------	------------

Filing Date	February 18, 2004
-------------	-------------------

First Named Inventor	Rajashree Joshi-Hangal
----------------------	------------------------

Art Unit	1614
----------	------

Examiner Name	Not yet assigned
---------------	------------------

Sheet

7

of

7

Attorney Docket Number	12636-303.301
------------------------	---------------

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*